K003193

NOV - 7 2000

510(k) SUMMARY

Date Prepared	October 10, 2000
510(k) No.	
Submitter	Baxter Healthcare Corporation Hyland Immuno 550 North Brand Boulevard Glendale, CA 91203
Contact	Arlene Vidor Vice President, Regulatory Affairs, North America
Device Name	**DuploGrip** Accessory Grip
Common/Usual/ Classification Name	Syringe, Piston
Predicate Device	**Duploject** Double-Barreled Syringe Applicator Device K973510 Baxter AG
Device Description	The **Duploject** Double-Barreled Syringe Applicator device (predicate device), which consists of two disposable syringes, a syringe holder with a common plunger, joining Y-piece and application cannulae, is used for the application of two non-homogenous solutions onto a surgical site. The **DuploGrip** Accessory Grip (modified device) is a single-use device that is used as an ergonomic enhancement to the **Duploject** Double-Barreled Syringe Applicator device. No modifications were made to the **Duploject** device to accommodate the addition of the accessory grip; therefore, the principle of operation, one-to-one delivery of fluids and mixing mechanism remain unchanged from the predicate device. The modified device has been shown to be substantially equivalent to the predicate device through a series of bench-top tests, in which the ability to deliver fluids through various applicator tips was shown to be equivalent to the predicate device.
Intended Use	The **DuploGrip** Accessory Grip, in conjunction with the **Duploject** Double-Barreled Syringe Applicator device, is intended for the simultaneous delivery of two non-homogenous fluids or solutions onto a surgical site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2000

Ms. Arlene Vidor
Vice President, Regulatory Affairs
North America
Baxter Healthcare Corporation
Hyland Division
550 North Brand Boulevard
Glendale, California 91023

Re: K003193
Trade Name: DuploGrip
Regulatory Class: II
Product Code: FMF
Dated: October 11, 2000
Received: October 12, 2000

Dear Ms. Vidor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number K003193

Device Name **DuploGrip** Accessory Grip

Indications for Use The **DuploGrip** Accessory Grip, in conjunction with the **Duploject** Double-Barreled Syringe Applicator device, is intended for the simultaneous delivery of two non-homogenous fluids or solutions onto a surgical site.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

Patricia Cusenta
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003193